JUN 1 3 2001

Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K011250

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4152

Contact Person: Ann Quinn

Date 510(k) prepared: April 23, 2001

2. Device Name

Trade or Proprietary Name: *Vitros* Immunodiagnostic Products HBsAg Controls
Common Name: HBsAg controls
Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed).

3. Predicate Device

The *Vitros* Immunodiagnostic Products HBsAg Controls are substantially equivalent to Boston Biomedica, Inc. ACCURUN 1® Multi-Marker Positive Control (BK930027).

4. Device Description

The *Vitros* Immunodiagnostic System uses luminescence as the signal in the qualitative detection of HBsAg in human serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The *Vitros* Immunodiagnostic Products range of products, in this case *Vitros* Immunodiagnostic Products HBsAg Reagent Pack and *Vitros* Immunodiagnostic Products Calibrator, which are combined by the *Vitros* Immunodiagnostic System to perform a *Vitros* assay. The *Vitros* Immunodiagnostic Products HBsAg Reagent Pack and Calibrator have been submitted for FDA review in PMA P000044.

2. The *Vitros* Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The *Vitros* Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the *Vitros* System in each assay. The *Vitros* Immunodiagnostic Products Signal Reagent and *Vitros* Immunodiagnostic Products Universal Wash Reagent were cleared as part of the *Vitros* Immunodiagnostic Products Total T3 510(k) pre-market notification (K964310).

The *Vitros* System and common reagents are dedicated specifically only for use with the *Vitros* Immunodiagnostic Products range of immunoassay products.

5. Device Intended Use

The *Vitros* HBsAg Controls are intended for use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma (EDTA, heparin or citrate). The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.

6. Comparison to Predicate Device

The *Vitros* Immunodiagnostic Products HBsAg Controls are substantially equivalent to Boston Biomedica, Inc. ACCURUN 1® Multi-Marker Positive Control (BK930027).

Table 1 lists the similarities and differences of the device characteristics between the *Vitros* HBsAg Controls and the predicate device.

Table 1 Characteristics of the Controls

Characteristics	New Device	Predicate Device
Intended use	For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma (EDTA, heparin or citrate). The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.	ACCURUN 1® controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN 1 Multi-Marker Positive Controls have been formulated for use with *in vitro* diagnostic test kits for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2), antibodies to Human T-Lympnotropic Virus Types I and II (HTLV I and II), antibodies to Hepatitis B Core Antigen (HBcAg), antibodies to Hepatitis C Virus (HCV), antibodies to Cytomegalovirus (CMV), and Hepatitis B Surface Antigen. A negative control for these analytes is available separately from BBI®.
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum or plasma with added stabilizers and preservative.
Control levels	Positive and negative	Positive
Expected values	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent lots. Values are lot specific.	As stated in the package insert, ACCURUN 1 controls do not have assigned values, but are formulated to produce positive reactivity in the listed manufacturer's assays. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent lot numbers, and different laboratores. Each laboratory should establish its own range of acceptable values for each analyte.

7. Conclusions

The information presented in the pre-market notification demonstrates that the *Vitros* HBsAg Controls are substantially equivalent to the predicate device Boston Biomedica, Inc. ACCURUN 1® Multi-Marker Positive Control which was cleared by FDA (BK930027).

The information presented in the premarket notification provide a reasonable assurance that the *Vitros* HBsAg Controls are safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1 2001

Ms. Ann M. Quinn
Regulatory Affairs Manager
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: 510(K) Number: K011250
Trade/Device Name: *Vitros* Immunodiagnostic Products HBsAg Controls
Regulation Number: 862.1660
Regulatory Class: I
Product Code: JJX, MJY, MJX
Dated: April 23, 2001
Received: April 24, 2001

Dear Ms. Quinn:

This letter corrects our substantially equivalent letter of June 13, 2001 regarding the incorrect Indications for Use Statement. The correct statement is included.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to

your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Intended Use

510(k) Number (if known):

Device Name: *Vitros* Immunodiagnostic Products HBsAg Controls

Indications for Use: For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum. The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011250